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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,648

12/05/2003

Young Kweon Choi

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,648	CHOI ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Previous Rejections

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

At least one new ground of rejection follows which was not necessitated by Applicant's amendment. Accordingly, this action is NON-FINAL.

Informalities

The following informalities are noted and should be corrected in responding to this Office action:

- a) claims 3 and 13, ninth line of each claim, in each instance "the" before "(meth)acrylic" should be changed to --- a ---;
- b) claim 3, tenth line "the" at the end of the line should be deleted;
- c) claim 3, seventh line, immediately after the semicolon there should be inserted --- and ---; and
- d) claim 13, tenth line, "the" before "polyvinylpyrrolidone" should be deleted.

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Duplicate Claim Warning

Applicant is advised that should claim 3 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "polyphosphate phosphonates" in claim 11 is non-sequitur. The examiner believes applicant intended to recite --- polyphosphates, phosphonates ---; if this is the case, correction is required. If not, explanation is required as to what a "polyphosphate phosphonate" is.

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Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US Pub. 2004/0105834).

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The prior art discloses tooth whitening strips (patches) comprising a hydrogel layer containing a water-swellaable, water-insoluble polymer, a hydrophilic polymer, and an oligomer capable of hydrogen binding to the hydrophilic polymer. Working example 1 (paragraph [0173] at page 15) discloses a hydrogel composition containing 9 wt % Eudragit L 100-55 (a 1:1 methacrylic acid/methacrylate copolymer: see paragraph [0072]), 44 wt% polyvinylpyrrolidone, polyethylene glycol (also a plasticizer: see paragraph [0088]), and hydrogen peroxide. Since the composition is extruded, the individual components would be intimately mixed such that hydrogen bonding of the polymers and the peroxide would be reasonably expected to inevitably occur to at least a small degree (particularly given the reference acknowledges that hydrogen bonding occurs between the oligomer and the hydrophilic polymer under the conditions employed).

The working example includes only one polymer in its erodible backing layer, i.e., Eudragit S 100 (a 1:2 methacrylic acid/methacrylate copolymer: see paragraph [0072]). The prior art thus differs from the instant claims insofar as it does not disclose, in the form of a discrete preferred embodiment, a tooth whitening strip simultaneously containing the claimed polymer complexes and having an erodible backing comprising a mixture of a hydrophilic polymer and a film-forming polymer. Blends are clearly taught however at paragraph [0134]; mixtures of polymers may be selected to tailor the rate of erosion to the particular hydrogel layer used (last five lines of paragraph [0136]). Particularly identified species include hydroxypropylcellulose (paragraph [0137]) and Eudragit copolymers (paragraph [0136]), the same species recited by applicant in dependent claim 5.

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Various other conventional additives may be included, e.g., polyphosphates and pyrophosphates as recited by instant claims 11 and 12 (paragraph [0109]), and citric acid as a pH adjusting (and thus peroxide stabilizing) agent (paragraph [0129]) as also required by instant claim 11. It would have been obvious to have included any of these conventional agents for their art-recognized purposes per these teachings.

The prior art also differs from instant claims 14 and 15 insofar as discretely disclosed strips containing the claimed mixture of polymers and having the particular thickness dimensions recited therein are not specifically illustrated. Working example 1 discloses a patch thickness of 350um, which is slightly outside the 300um upper range recited by instant claims 14 and 15. The prior art does teach, however, that overall thickness may be varied from 50 to 800um (paragraph [0158]).

Generally, it is prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. *See In re Aller*, 105 USPQ 233, 235 (CCPA 1955); *In re Boesch*, 205 USPQ 215 (CCPA 1980); and *In re Peterson*, 315 F.3d 1325 (CA Fed 2003). Accordingly, it would have been obvious to have varied the thicknesses of the various sublayers of the prior art strips to tailor them to particular uses and thus to have arrived at the instantly claimed values in doing so, motivated by the desire to determine optimal and/or workable thicknesses through the application of routine experimentation per the reasoning of the cited precedent.

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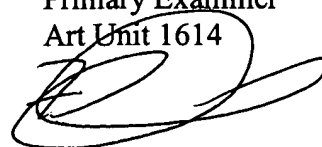
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to be 'F. Krass', is written over the printed name and title of the examiner.